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| EXAMINER | |
|---|---|
| FLORY, CHRISTOPHER A | |
| ART UNIT | PAPER NUMBER |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/698,232 | HAMILTON ET AL. | |
| | Examiner | Art Unit | |
| | CHRISTOPHER A. FLORY | 3762 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *25 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-15,17-31,33-47,51 and 52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15,17-31,33-47,51 and 52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 25 July 2008 has been entered.

### *Response to Arguments*

2. Applicant's arguments filed 25 July 2008 have been fully considered but they are not persuasive.

3. Applicant first argues that Secker does not teach deriving a set of segments, but rather merely describes pre-processing to remove abnormal measurements but leaving the signal as a whole. However, Applicant also readily admits on page 17, paragraph 3 that Secker teaches windowing the fetal heart rate to calculate rate variability and amplitude over time windows of e.g. one minute (column 23, lines 10-25), which the Examiner sees as a disclosure of segmenting or deriving a set of segments of the signal as a whole, since analysis is performed on each individual segment.

4. Applicant also argues that Secker does not teach each segment having a time duration since Secker performs analysis in the frequency domain. First, it is noted again that Applicant has pointed out that Secker bases the frequency domain analysis

on data collected over blocks determined by a selectable time window of data collected in the time domain (col. 23, lines 10-15). As such, even though Secker performs analysis on frequency data, the sets of segments represent data of the time domain fetal heart rate signal that are determined by a time window. It is also noted that the time domain itself is nowhere found in the present claim limitations, simply that the segments have a time duration (e.g. one minute as pointed out by Applicant).

5. In order to clarify that which is considered a "bounded area," the Examiner points to the portion of the Secker reference cited by the Applicant (col. 23, line 8 through col. 24, line 47), which describes sets of heart rate data segmented by a selectable time window, the beginning and ending boundaries of that time window defining the bounded area. The Secker data is also bounded by frequency limitations.

6. Regarding Applicant's argument that Secker does not teach processing the set of segments by virtue of the fact that the segments themselves are not taught, it is noted that this reasoning is considered moot since it has been shown that Secker does in fact teach the bounded segments.

7. The §103 rejection under Frank in view of Secker stands for the same reasons presented above. It is additionally noted that Frank very clearly discloses segmenting and analyzing a fetal heart rate on a beat-to-beat basis using an adjustable time window in the abstract of the disclosure.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-15, 17-31, 33-47, 51 and 52 are rejected under 35 U.S.C. 102(b) as being anticipated by Secker et al. (US 5,442,940, hereinafter Secker'940).

Regarding claims 1, 17, 33, 51 and 52, Secker'940 discloses a method and device for segmenting a fetal heart rate signal to identify heart rate feature events (TITLE, ABSTRACT) comprising a sensor for generating and receiving a fetal heart rate signal including a sequence of sample points (column 14, lines 52-58); Processing the fetal heart rate signal to generate a set of segments each corresponding to a respective portion of the fetal heart rate signal enclosable in a bounded area commencing at a start sample point and terminating at an end sample point (column 18, lines 37-49) wherein the bounded area of each segment has a time duration determined on a basis of at least one characteristic of the fetal heart rate signal (column 11, line 45 through column 12, line 24; column 23, lines 10-15); processing the fetal heart rate signal to identify a plurality of distinct sections and associate sections with respective labels conveying heart rate features (column 15, lines 35-48 and 58-68); and releasing a signal indicative of said plurality of sections (Fig 21 and related paragraphs).

Further regarding claim 33, Secker'940 discloses a computer readable storage medium (abstract; column 4, lines 36-55).

Regarding claims 2, 18 and 34, Secker'940 discloses one of acceleration, deceleration and baseline events (column 2, lines 39-45; column 4, lines 12-29; column 16, lines 11-23).

In reference to claim 3, 4, 7, 8, 19, 20, 23, 24, 35, 36, 39 and 40, a trapezoid is defined as a quadrilateral with two sides parallel and a parallelogram is defined as a quadrilateral with opposite sides parallel (and therefore opposite angles equal) (see http://mathworld.wolfram.com/Trapezoid.html). Secker'940 shows segmenting the detected heart rate into rectangular partitions (see Fig. 21), and thus such partitions fit the definition of the trapezoid.

Regarding claims 5, 6, 21, 22, 37 and 38, Secker'940 shows a polynomial approximation of the sample points being a line of best fit (Fig. 6b and related paragraphs).

In reference to claims 9-11, 25- 27 and 41-43, an individual's heart rate will inherently possess a certain drift and/or excursion dependent upon an individual's activity level and/or health, evidenced by expression in frequency domain as explained in the ABSTRACT.

Regarding claims 12, 28 and 44, Secker'940 discloses a list of labeled sections including a plurality of data elements, each being associated with one of an acceleration event, a deceleration event, and a baseline (Fig. 17b and related paragraphs; Figs. 18, 19).

Regarding claims 13, 29 and 45, Secker'940 sows a recursive process (Fig. 5, step 57; Fig. 22b, step 175).

Regarding claims 14, 15, 30, 31, 46 and 47, the recursive process of Secker'940 as described above inherently includes leaving at least one remaining portion of said fetal heart rate signal excluded from the enclosed portion as only one portion is enclosed by each iteration of the process, wherein the process is repeated until the condition that the entire heart signal has been enclosed in a bounded area is met.

### *Claim Rejections - 35 USC § 103*

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 1, 3-15, 17, 18-30, 33, 35-40, 45, 46, 51 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frank et al. (US 5,042,499, hereinafter Frank'499) in view of Secker'940.

In reference to claims 1 & 17, Frank'499 discloses a method for segmenting a fetal heart rate signal to identify heart rate feature events comprising of receiving a heart rate signal including a sequence of sample points (see column 1, lead lines 26-31 & column 4, lead lines 24-34) and the use of a processing unit for processing the heart rate signal to generate a set of segments (see column 4, lead lines 24-31). Frank'499 also discloses each a segment being formed by enclosing a portion of said heart rate

signal in a respective bounded area, the bounded area commencing at a start sample point of said heart rate signal and terminating at an end sample point of said heart rate signal wherein the sample points between said start sample point and end sample point lie within said bounded area (see fig. 8 & column 6, lead lines 40-44). Frank'499 discloses processing the set of segments to generate a plurality of sections, each section being indicative of a heart rate feature and releasing a signal indicative of said plurality of sections (see column 1, lead lines 13-23 & fig. 8). The Frank'499 processor alone performs the function of multiple processing units.

In reference to claim 33, Frank'499 discloses a method for segmenting a heart rate signal to identify heart rate feature events comprising of receiving a heart rate signal including a sequence of sample points (see column 1, lead lines 26-31 & column 4, lead lines 24-34) and the use of a processing unit for processing the heart rate signal to generate a set of segments (see column 4, lead lines 24-31). Frank'499 also discloses each segment being formed by enclosing a portion of said heart rate signal in a respective bounded area, the bounded area commencing at a start sample point of said heart rate signal and terminating at an end sample point of said heart rate signal wherein the sample points between said start sample point and end sample point lie within said bounded area (see fig. 8 & column 6, lead lines 40-44). Frank'499 teaches processing the set of segments to generate a plurality of sections, each section being indicative of a heart rate feature and releasing a signal indicative of said plurality of sections (see column 13-23 & fig. 8). The Frank'499 processor alone performs the function of multiple processing units. Frank'499 does not explicitly teach placing all of

the aforementioned information onto a computer readable storage medium. However it would have been obvious to one of ordinary skill in the art to introduce the use of a computer readable medium to allow for the transport of data from one device to another.

Further regarding claims 1, 17 and 33, for a digital signal, each digital data point of a measured heart rate signal as disclosed in Frank'499 is inherently based on a corresponding portion of the heart rate signal, and further is inherently enclosable in a bounded area (e.g. the sampling rate of the digital system determines a left and right time boundary for each data point collected). Frank does not expressly disclose that the length of the bounded area is determined on a basis of the fetal heart rate signal. In the same field of endeavor, Secker'940 teaches fetal heart rate variability calculations performed in a spectral window with adaptive width limits based on the frequency of the fetal heart rate to increase accuracy of the heart rate calculation (column 11, line 45 through column 12, line 13). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system and method of Frank'499 with the adaptive width window as taught by Secker'940 to provide the Frank'499 invention with the same advantage of more accurately calculating fetal heart rate and variability.

Still further regarding claims 1 and 17, Frank'499 discloses the invention substantially as claimed, but does not expressly disclose associating sections of the signal with labels, at least some labels conveying heart rate features. In the same field of endeavor, Secker'940 teaches using indicators to indicate the quality of the heart rate signal as well as the heart rate value (column 15, lines 35-48 and 58-68). Therefore, it

would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method and device of Frank'499 to include a label indicating the quality of the heart rate signal as well as the heart rate value as taught by Secker'940 to provide Frank'499 with the same advantages of notifying the attendant spectator to the quality and value of the heart rate signal.

In reference to claim 3, 4, 8, 19, & 20, a trapezoid is defined as a quadrilateral with two sides parallel and a parallelogram is defined as a quadrilateral with opposite sides parallel (and therefore opposite angles equal) (see http://mathworld.wolfram.com/Trapezoid.html). The Frank'499 device teaches segmenting the detected heart rate into rectangular partitions (see figs. 8-10), and thus such partitions fit the definition of the trapezoid.

In reference to claims 5 & 20, they are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Frank'499 because the entire heart rate signal is a sampling of an actual heart rate, each segment presented would inherently possess an approximate polynomial number of sample points. If not inherent it would have been obvious to one of ordinary skill in the art to use such an approximation because to reproduce an exact replica of a signal one would have to sample said signal infinitely and the presentation means use to present said signal would have to be capable of presenting said infinite number of sample points.

In reference to claims 6, 21, 22, 37, & 38 Frank'499 discloses the invention substantially as claimed, but does not expressly disclose the use of a best-fit line. However in the field of graphical data analysis the use of a best-fit line is quite common

and well known in the art. Thus it would have been obvious to one of ordinary skill in the art to apply a line of best fit to the heart rate data to reveal a trend of some sort. It would have also been obvious to one of ordinary skill in the art to introduce the use of a computer readable medium to allow for the transport of data from one device to another.

In reference to claim 7, 23, 35, 36 and 39, Frank'499 discloses segmenting the detected heart rate into rectangular partitions (see figs. 2, 3, & 6B), and thus such partitions fit the definition of the trapezoid. Frank'499 also teaches a method wherein a trapezoid associated with a given segment of said heart rate signal has a height conditioned at least in part on the basis of the variability of at least part of said heart rate signal (see figs. 8-10), however Frank'499 does teach bounded area is a trapezoid that can be defined as a parallelogram (see figs. 2, 3, & 6B).

In reference to claim 8 & 24, Frank'499 discloses having the least part of a heart rate signal enclosed within a trapezoid (see figs. 1 & 8-10).

In reference to claims 9-11 and 25- 27, an individual's heart rate will inherently possess a certain drift and/or excursion dependent upon an individual's activity level and/or health (see column 19, lead lines 65-68 and column 10, lead lines 10-26).

In reference to claim 12 & 28, Frank'499 discloses a method wherein a signal indicative of a plurality of heart rate sections includes a list of labeled sections including a plurality of data elements, each data element being associated with a respective section and including a label component, the label component being indicative of either one of an acceleration event, deceleration event and baseline event (see column 6, lead lines 32-34 & column 23, lead lines 63-65).

In reference to claim 13 & 29, Frank'499 discloses providing a picture of an individual's heart rate continuously, over an extended period of time. To do such one would inherently use a recursive process (see column 1, lead lines 26-31).

In reference to claim 14 & 30, Frank'499 discloses a method wherein said recursive process includes forming a segment of said set of segment by enclosing a portion of said heart rate signal in a bounded area, thereby leaving at least one remaining portion of the heart rate signal, the at least one remaining portion including sample points of the heart rate signal excluded from the enclosed portion.

In reference to claim 40, Frank'499 discloses having the least part of a heart rate signal enclosed within a trapezoid (see figs. 1 & 8-10).

In reference to claim 45, Frank'499 discloses providing a picture of an individual's heart rate continuously, over an extended period of time. To do such one would inherently use a recursive process (see column 1, lead lines 26-31).

In reference to claim 46, Frank'499 discloses a method wherein said recursive process includes forming a segment of said set of segment by enclosing a portion of said heart rate signal in a bounded area, thereby leaving at least one remaining portion of the heart rate signal, the at least one remaining portion including sample points of the heart rate signal excluded from the enclosed portion.

In reference to claims 51 and 52, Frank'499 discloses a fetal monitoring system comprising a sensor for receiving a signal indicative of a fetal heart rate an apparatus suitable for monitoring the condition of a fetus, said apparatus comprising of an input coupled to said sensor for receiving a signal indicative of a fetal heart rate (see

abstract). The Frank'499 device teaches a feature detection module coupled to said input, said feature detection module implementing a processing unit adapted for processing the heart rate signal to generate a set of segments, each segment being generated by enclosing a portion of said heart rate signal in a respective bounded area, the bounded area commencing at a start sample point of said heart rate signal and terminating at an end sample point of said heart rate signal, wherein the sample points between said start sample point and end sample point lie within said bounded area (see figs. 8-10 & column 6, lead lines 32-34 & column 23, lead lines 63-65). Frank'499 teaches a processing unit adapted for processing the set of segments to generate a plurality of sections, each section being indicative of a heart rate feature (see figs. 8-10 and column 6, lead lines 32-34 & column 23, lead lines 63-65)° Frank'499 teaches a post processing module coupled to said a feature detection module, said post processing module being adapted for deriving information on the basis of the heart rate features associated with said set of segments (see fig 1, & column 3, lead lines 11-26). Frank'499 teaches an output for releasing the information derived from the heart rate features associated set of segments (see fig. 1) as well as an output unit coupled to the output for said apparatus, said output unit being suitable for displaying the information derived from the heart rate features associated with said set of segments (see figs.1 & 8-10 and column 6, lead lines 32-34 & column 23, lead lines 63-65).

Further regarding claims 51 and 52, for a digital signal, each digital data point of a measured heart rate signal as disclosed in Frank'499 is inherently based on a corresponding portion of the heart rate signal, and further is inherently enclosable in a

bounded area (e.g. the sampling rate of the digital system determines a left and right time boundary for each data point collected). Because each data point is both bounded and corresponds to a portion of the heart rate signal, it can be said that the bounded area length would inherently be based on and associated with some characteristic of that portion of the signal.

12. Claims 2, 18, 34, and 41-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frank'499 in view of Secker'940, and further in view of Jelliffe et al. (US 2003/006090 A1).

Regarding claims 2, 18 and 34, Frank'499 discloses the invention substantially as claimed, but does not expressly disclose the selection of features based on acceleration, deceleration and baseline events. In the same problem solving area, Jelliffe et al. teaches the selection of events based on acceleration and baseline events, such a selection would inherently provide the user with deceleration events as well (see pp. [0024]). Thus it would have been obvious to one of ordinary skill in the art to combine the aforementioned aspects of the Frank'499 device with the event capturing methods of the Jelliffe et al. publication it indicate to the user and/or medical practitioner where exactly the possibly problem causing event(s) may occur. It would also have been obvious to one of ordinary skill in the art to introduce the use of a computer readable medium to allow for the transport of data from one device to another.

In reference to claims 41-43, an individual's heart rate will inherently possess a certain drift and/or excursion dependent upon an individual's activity level and/or health (see column 19, lead lines 65-68 and column 10, lead lines 10-26).

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Christopher A. Flory/

2 September 2008

**/George Manuel/**
Primary Examiner